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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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03/10/2004

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EXAMINER

SHAY, DAVID M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 03/10/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,132

Applicant(s)

Belo, Jr

Examiner

J. Shay

Group Art Unit

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE — 3 — MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on November 24, 2003.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-27 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-27 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 13
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejections set forth in the previous office action are hereby repeated.

Claims 1-6, 11, 12, 18, 23, 26, and 27 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mueller.

See figures 3A-3C and column 5, line 56 to column 8, line 48; wherein the infusion device is the barb, also conical element 21 can perform a sealing function.

Claims 1-6, 9-12, 18, 23, 26 and 27 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Murphy-Chutorian et al.

See figures 2-5 and 8 and column 4, line 47 to column 5, line 12; and column 15, line 38 to column 22, line 16.

Claims 1, 7, 8, and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller in combination with Kalloo et al. Mueller et al teach a device such as claimed except for the balloons (note other structure predicated on the balloons e.g. inflation lumen are also not necessarily taught thereby). Kalloo et al teach the use of a dual balloon stabilizing means to aid in the placement of a surgical device. It would have been obvious to the artisan of ordinary skill to employ the balloons of Kalloo et al in the device of Mueller, since this would enable the stabilization thereof with respect to e.g. the chest wall, thus producing a device such as claimed.

Claims 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller in combination with Kalloo et al. The teachings of Mueller and Kalloo et al and the motivations for combinations are essentially those already set forth regarding claims 1, 7, 8, and 12-17 above. Thus it would have been obvious to the artisan of ordinary skill to combine these old and well

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known teachings and to employ a plurality of barbs, since this is merely the provision of multiple structures for multiplied effect and is notorious in the art, thus producing a method such as claimed.

Applicant asserts that Mueller does not teach a “medicament delivery member having an outlet and disposed at the distal portion, terminating in a tissue engaging surface and having at least one deployable member positioned therein”. The examiner must respectfully disagree, “Mueller disclosed a device having a tapered dilator tip” (see the instant response, page 8, first sentence). In order to dilate, the device must force the tissue open, thus applying pressure thereto and thereby stabilizing the tissue with respect to the dilator due to the application of pressure. Since this occurs while medication is being infused the tissue is both stabilized and sealed while medication is infused (see, e.g. column 7, lines 18-42). Thus the limitations of claims 1, 12, 18, and 23 are met thereby. Clearly the optical fiber of Mueller is flexible and thus fulfills the flexibility language of claim 26.

Regarding Murphy-Chutorian et al, applicant argues that no deployable tissue stabilizing member is disclosed thereby. The examiner must respectfully disagree. A careful reading of Murphy-Chutorian et al reveals, “suction may be provided at the target surface to stabilize the drug delivery and/or laser apparatus” (see column 5, lines 10-12). Since vacuum fixation is also contemplated by applicant (see the originally filed disclosure, page 36, last paragraph and Figures 39A and 39B), this clearly reads on applicants claimed tissue stabilizing member. Since the device of Murphy-Chutorian et al injects the medicament into the claimed, via a piercing needle, this needle will act as a sealing member in the same sense a needle in an intramuscular injection, seals and prevents the medicament from leaking out the channel the needle has formed.

Regarding the rejection under 35 USC 103, applicant appears to argue that Kalloo fails to disclose a flexible distal portion terminating in a tissue engaging surface having at least one deployable biasing member positional thereon. The examiner must respectfully disagree. The Kalloo device is flexible (see the instant response, page 13, first full paragraph, sixth sentence) and teaches two balloons (see Kalloo, Figure 11) and anchors the flexible member, thereby biasing it in an anchored position (see Kalloo, the paragraph bridging pages 4 and 5). Further the device of Mueller needs to be motionless with respect to the chest in order to properly detect systole via the disclosed pressure transducers. Therefore the motivations put forth by the examiner are wholly proper and not based on impermissible hindsight as alleged by applicant.

Applicant's arguments filed November 24, 2003 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication should be directed to David Shay at telephone number 308-2215.



Shay/DI

February 9, 2004

**DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330**